Drug Chemistry Validation and New Method Validation

1. Purpose and Scope

Validation of procedures used in Forensic Drug Chemistry Analysis are essential to ensure absolute accuracy and precision of results. New Instrumentation, software and methods will be validated using accepted scientific principles prior to implementation on casework.

2. Definitions

"Gold Standard"	Definitive benchmark test
Accuracy	A measure of the difference (bias) between the average of the readings from a measurement system and a corresponding benchmark or master.
Declaration of Conformity	Complies with the essential requirements and product standards ccording to ISO/IEC Guide 22 and CEN/CENELEC EN 45014.
Precision	The reproducibility or degree to which further measurements or calculations show the same or similar results.
Quality Assurance	those planned and systematic actions necessary to provide sufficient data that a laboratory's products and services will satisfy defined requirements for quality.
Validation:	the process of experimentation and review which establish the efficacy and reliability of a new or modified technique or procedure.

3. Procedures

3.1 Validation of Existing Methods

Methods used in the analytical analysis of scheduled substances and identification of compounds in the Forensic Drug Chemistry laboratory are the accepted "gold standard" by the Forensic community. In fact,

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Procedures (Continued)

they have been in use by this laboratory for over 25 years. Validation continues on a daily basis by continuing the use of NIST traceable standards to verify instrument performance.

3.2 Validation of New Equipment

New instruments purchased based on previous validated techniques such as FTIR, UV-Vis, GC/MS will be validated by the manufacture according to their Declaration of Conformity. A copy of this Declaration will be kept in the instrument logbook. At least 10 NIST traceable standards will be be run on the instrument to check total system reliability from sampling to reporting. Each day of use NIST traceble standards or mixes will be run on the appropriate instrument for continual validation.

4. Notes

5. Records

No records are created by this procedure.

6. Policy References

Technical requirements	5
General	5.1
Test and calibration methods and method validation	5.4

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7. References

7.1 Related Procedures

No procedures are related to this procedure.

7.2 Reference Documents

No documents are referenced by this procedure.